# DTO3 Rec'd PCT/PTO 1 7 MAR 2005

PTO-1390 (Rev. 02-2005) Approved for use through 3/31/2007. OMB 0551-0021 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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## TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER 20747/270 U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

PRIORITY DATE CLAIMED

PCT/GB2003/004117

INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE 17 September 2003 (17.09.2003)

17 September 2002 (17.09.2002)

TITLE OF INVENTION See 1 in Addendum	
APPLICAN'	T(S) FOR DO/EO/US THOMSON, Axel Andreas
Applicant	herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:
1. 🔀 Т	his is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.
2. TI	his is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.
	his is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items 5), (6), (9) and (21) indicated below.
4. 🗓 т	he US has been elected (Article 31).
5. 🗓	A copy of the International Application as filed (35 U.S.C. 371(c)(2))
	a. is attached hereto (required only if not communicated by the International Bureau).
	b. X has been communicated by the International Bureau.
	c. is not required, as the application was filed in the United States Receiving Office (RO/US).
6.	An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
	a. is attached hereto.
	b. has been previously submitted under 35 U.S.C. 154(d)(4).
7. X	Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
	a. are attached hereto (required only if not communicated by the International Bureau).
i.	b. have been communicated by the International Bureau.
	c. have not been made; however, the time limit for making such amendments has NOT expired.
-	d. $\overline{X}$ have not been made and will not be made.
8.	An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9.	An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10.	An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).
Items 11 to 20 below concern document(s) or information included:	
11. 🗓	An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. 🔲	An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. X	A preliminary amendment.
14.	An Application Data Sheet under 37 CFR 1.76.
15. 🔲	A substitute specification.
16. 🗌	A power of attorney and/or change of address letter.
17. X	A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.
18.	A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. 🔲	A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
	Other items or information: See Attachment 2

USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO-1390 (Rev. 02-2005)

Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

INTERNATIONAL APPLICATION NO. U.S. APPLICATION NO. (if known, see 37 CFR 1.5) ATTORNEY'S DOCKET NUMBER 826 PCT/GB2003/004117 20747/270 The following fees have been submitted CALCULATIONS PTO USE ONLY 21. 💢 Basic national fee.....\$300 300.00 22. If International preliminary examination report prepared by USPTO and all claims satisfy provisions of 200.00 \$ All other situations \$200 23. Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an 400.00 International Searching Authority......\$100 International Search Report prepared and provided to the Office..... \$ All other situations......\$500 \$ 900.00 TOTAL OF 21, 22 and 23 = Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. Total Sheets Extra Sheets Number of each additional 50 or fraction RATE thereof (round up to a whole number) -23 /50 = 0.00 77 - 100 = x \$250 Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest \$ 130.00 claimed priority date (37 CFR 1.492(h)). **CLAIMS** NUMBER FILED NUMBER EXTRA RATE \$ Total claims \$ 50 \$ - 20 = 0.00 17 0 \$ Independent claims - 3 = 2 \$200 400.00 5 MULTIPLE DEPENDENT CLAIM(S) (if applicable) \$360 \$ 0.00 **TOTAL OF ABOVE CALCULATIONS =** \$ 1,430.00 Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. 0.00 SUBTOTAL = \$ 1,430.00 Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest \$ 0.00claimed priority date (37 CFR 1.492(i)). **TOTAL NATIONAL FEE =** \$ 1,430.00 Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied \$ 0.00 by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property TOTAL FEES ENCLOSED = 1,430.00 Amount to be \$ refunded: Amount to be \$ charged:  $\mathbf{x}$ A check in the amount of \$ 1,430.00 to cover the above fees is enclosed. Please charge my Deposit Account No. in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed. c. X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit 14-1138 . A duplicate copy of this sheet is enclosed. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. SEND ALL CORRESPONDENCE TO: Edwin V. Merkel Nixon Peabody LLP Edwin V. Merkel Clinton Square NAME P. O. Box 31051 Rochester, NY 14603-1051 REGISTRATION NUMBER United States of America

# Addendum

1. A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

### Attachment 2

UNSIGNED Combined Declaration and Power of Attorney. Verified Statement Re Sequence Listing.

DOCKET NO.: 20747/270

APPLICANT(S): THOMSON, Axel Andreas

TITLE: A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE

EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

Certificate is attached to the Preliminary Amendment

(6 pages) of the above-named application.

"EXPRESS MAIL" NUMBER: EV522795394US

DATE OF DEPOSIT: March 17, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Mail Stop: PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Shawn Lockett

(Typed or printed name of person mailing paper or fee)

Signature of person mailing paper or fee)

DOCKET NO.: 20747/270

APPLICANT(S): THOMSON, Axel Andreas

TITLE: A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE

EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

Certificate is attached to the Unsigned Combined Declaration and Power of Attorney (2 pages) of the above-named application.

"EXPRESS MAIL" NUMBER: EV522795394US

DATE OF DEPOSIT: March 17, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Mail Stop: PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Shawn Lockett

(Typed or printed name of person mailing paper or fee)

(Signature of person mailing paper or fee)

DOCKET NO.: 20747/270

APPLICANT(S): THOMSON, Axel Andreas

TITLE: A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE

EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

Certificate is attached to the Sequence Listing on Diskette and Verified Statement re Sequence Listing of the above-named application.

"EXPRESS MAIL" NUMBER: EV522795394US

DATE OF DEPOSIT: March 17, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Mail Stop: PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Shawn Lockett

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(Signature of person mailing paper or fee)

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#### EXPRESS MAIL CERTIFICATE

DOCKET NO.: 20747/270

APPLICANT(S): THOMSON, Axel Andreas

TITLE: A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE

EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

Certificate is attached to the Transmittal Letter to the U.S. Designated/Elected Office (DO/EO/US) of the above-named application.

"EXPRESS MAIL" NUMBER: EV522795394US

DATE OF DEPOSIT: March 17, 2005

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DOCKET NO.: 20747/270

APPLICANT(S): THOMSON, Axel Andreas

TITLE: A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE

EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT

Certificate is attached to the Information Disclosure Statement with PTO-1449 forms (3 pages) of the above-named application.

"EXPRESS MAIL" NUMBER: EV522795394US

DATE OF DEPOSIT: March 17, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Mail Stop: PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Shawn Lockett

(Typed or printed name of person mailing paper or fee)

(Signature of person mailing paper or fee)